MEDICAL POLICY

POLICY TITLE	**AQUEOUS SHUNTS AND STENTS FOR GLAUCOMA**
POLICY NUMBER	**MP 2.149**

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**2/1/2024**

I. POLICY

Shunts

Insertion of ab externo aqueous shunts approved by the U.S. Food and Drug Administration (FDA) may be considered **medically necessary** as a method to reduce intraocular pressure in members with glaucoma where medical therapy has failed to adequately control intraocular pressure.

Use of an ab externo aqueous shunt for all other conditions, including in members with glaucoma when intraocular pressure is adequately controlled by medications, is considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Stents

Insertion of ab interno aqueous stents approved by the U.S. Food and Drug Administration as a method to reduce intraocular pressure in members with glaucoma where medical therapy has failed to adequately control intraocular pressure, may be considered **medically necessary.**

Implantation of 1 or 2 U.S. Food and Drug Administration-approved ab interno stents in conjunction with cataract surgery may be considered **medically necessary** in members with mild-to-moderate open-angle glaucoma treated with ocular hypotensive medication.

Use of ab interno stents for all other conditions is considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

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Shunts and stents are only able to reduce intraocular pressure (IOP) to the mid-teens and may be inadequate when very low IOP is needed to reduce glaucoma damage.

Cross-reference:

MP 2.056 Ophthalmologic Techniques That Evaluate the Posterior Eye Segment for Glaucoma

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO:
Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies .

III. DESCRIPTION/BACKGROUND

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Glaucoma

Glaucoma is the leading cause of irreversible blindness worldwide and is characterized by elevated intraocular pressure (IOP). In 2020, glaucoma affected approximately 52.7 million individuals globally, with a projected increase to 79.8 million in 2040.1, Glaucoma has been reported to be 7 times more likely to cause blindness and 15 times more likely to cause visual impairment in Black individuals as compared to White individuals. In the U.S. in 2010, Black individuals had the highest prevalence rate of primary open angle glaucoma at 3.4% compared to 1.7% among White individuals.

In the primary (conventional) outflow pathway from the eye, aqueous humor passes through the trabecular meshwork, enters a space lined with endothelial cells (Schlemm canal), drains into collector channels, and then into the aqueous veins. Increases in resistance in the trabecular meshwork and/or the inner wall of the Schlemm canal can disrupt the balance of aqueous humor inflow and outflow, resulting in an increase in IOP and glaucoma risk.

Treatment

Ocular Medication

First-line treatment typically involves pharmacologic therapy. Topical medications either increase aqueous outflow (prostaglandins, alpha-adrenergic agonists, cholinergic agonists, Rho kinase inhibitors) or decrease aqueous production (alpha-adrenergic agonists, beta blockers, carbonic anhydrase inhibitors). Pharmacologic therapy may involve multiple medications, have potential side effects, and may be inconvenient for older adults or incapacitated patients.

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Surgery

Surgical intervention may be indicated in patients with glaucoma when the target IOP cannot be reached pharmacologically. Surgical procedures for glaucoma aim to reduce IOP from impaired aqueous humor drainage in the trabecular meshwork and/or Schlemm canal. Trabeculectomy (guarded filtration surgery) is the most established surgical procedure for glaucoma, which involves dissecting the conjunctiva, creating a scleral flap and scleral ostomy then suturing down the flap and closing the conjunctiva, allowing aqueous humor to directly enter the subconjunctival space. This procedure creates a subconjunctival reservoir, which can effectively reduce IOP, but commonly results in filtering “blebs” on the eye, and is associated with numerous complications (e.g., hemorrhage, scarring, hypotony, infection, leaks, bleb-related endophthalmitis) and long-term failure. Other surgical procedures (not addressed herein) include trabecular laser ablation, deep sclerectomy (which removes the outer wall of the Schlemm canal and excises deep sclera and peripheral cornea), and viscocanalostomy (which unroofs and dilates the Schlemm canal without penetrating the trabecular meshwork or anterior chamber). Canaloplasty involves dilation and tension of the Schlemm canal with a suture loop between the inner wall of the canal and the trabecular meshwork. This ab externo procedure uses the iTrack illuminated microcatheter (iScience Interventional) to access and dilate the entire length of the Schlemm canal and to pass the suture loop through the canal.

Insertion of shunts from outside the eye (ab externo) is another surgical option to lower IOP. Examples of ab externo devices cleared by the U.S. Food and Drug Administration (FDA) include the Ahmed, Baerveldt, Molteno, and EX-PRESS mini-shunt, which shunt aqueous humor between the anterior chamber and the suprachoroidal space. These devices differ by explant surface areas, shape, plate thickness, presence or absence of a valve, and details of surgical installation. Generally, the risk of hypotony (low pressure) is reduced with aqueous shunts compared with trabeculectomy, but IOP outcomes are worse than after standard guarded filtration surgery. Complications of anterior chamber shunts include corneal endothelial failure and erosion of the overlying conjunctiva. The risk of postoperative infection is lower with shunts than with trabeculectomy, and failure rates are similar (≈10% of devices fail annually). The primary indication for aqueous shunts is for failed medical or surgical therapy, although some ophthalmologists have advocated their use as a primary surgical intervention, particularly for selected conditions such as congenital glaucoma, trauma, chemical burn, or pemphigoid.

Minimally Invasive Glaucoma Surgeries

Minimally invasive glaucoma surgeries (MIGS) are alternative, less invasive techniques that are being developed and evaluated. MIGS, which use microscopic-sized equipment and smaller incisions, involve less surgical manipulation of the sclera and the conjunctiva compared with other surgical techniques. There are several categories of MIGS: miniaturized trabeculectomy, trabecular bypass, milder laser photocoagulation, and totally internal or suprachoroidal stents. Shunts and stents can be administered through an external flap of the conjunctiva and sclera (ab externo) or in a small incision in the cornea with the devices inserted through the anterior chamber of the eye (ab interno). Some ab interno microstents may be inserted with injectors.

Examples of ab externo devices are the Ahmed, Baerveldt, and EX-PRESS shunts. Examples of ab interno devices either approved or given marketing clearance by the FDA include the iStent, which is a 1-mm long stent inserted into the end of the Schlemm canal through the cornea and anterior chamber, iStent inject, and XEN gelatin stent.

Because aqueous humor outflow is pressure-dependent, the pressure in the reservoir and venous system is critical for reaching the target IOP. Therefore, some devices may be unable to reduce IOP below the pressure of the distal outflow system used (eg, <15 mm Hg) and are not indicated for patients for whom very low IOP is desired (eg, those with advanced glaucoma). It has been proposed that stents such as the iStent, iStent inject, and Hydrus Microstent may be useful in patients with early-stage glaucoma to reduce the burden of medications and problems with compliance. One area of investigation is patients with glaucoma who require cataract surgery. An advantage of ab interno stents is that they may be inserted into the same incision and at the same time as cataract surgery. Also, most devices do not preclude subsequent trabeculectomy if needed. It may also be possible to insert more than 1 stent to achieve desired IOP.

Regulatory Status

The regulatory status of the various ab externo and ab interno aqueous shunts and microstentsis summarized in Table 1.

The first-generation Ahmed™ (New World Medical), Baerveldt® (Advanced Medical Optics), Krupin (Eagle Vision), and Molteno® (Molteno Ophthalmic) ab externo aqueous shunts were cleared for marketing by the FDA through the 510(k) process between 1989 and 1993; modified Ahmed and Molteno devices were cleared in 2006. They are indicated for use “in patients with intractable glaucoma to reduce IOP where medical and conventional surgical treatments have failed.” The AquaFlow™ Collagen Glaucoma Drainage Device (STAAR Surgical) was approved by the FDA through the premarket approval process for the maintenance of the subscleral space following nonpenetrating deep sclerectomy. In 2003, the ab externo EX-PRESS® Mini Glaucoma Shunt was cleared for marketing by the FDA through the 510(k) process.

In 2016, the XEN® Glaucoma Treatment System (Allergan), which consists of the XEN45 Gel Stent preloaded into the XEN Injector, was cleared for marketing by the FDA through the 510(k) process as an ab interno aqueous stent for management of refractory glaucoma. The approval was for patients with refractory glaucoma who failed previous surgical treatment or for patients with primary open-angle glaucoma unresponsive to maximum tolerated medical therapy. The FDA determined that this device was substantially equivalent to existing devices, specifically the Ahmed™ Glaucoma Valve and the EX-PRESS® Glaucoma Filtration Device.

In 2018, the first microstent, the iStent® Trabecular Micro-Bypass Stent preloaded into the iStent inject device (Glaukos) was approved by the FDA through the 515(d) process for use in conjunction with cataract surgery for the reduction of IOP in adults with mild-to-moderate OAG currently treated with ocular hypotensive medication.

In August 2018, Alcon announced an immediate voluntary recall of the CyPass microstent, which had been approved by the FDA in 2016 for use in conjunction with cataract surgery in adults with mild-to-moderate OAG. The recall was based on 5 year postsurgery data from the COMPASS-XT long-term safety study. Results showed a statistically significant increase in endothelial cell loss among patients receiving the CyPass microstent compared with patients receiving cataract surgery alone.

Table 1. Regulatory Status of Aqueous Shunts and Stents

Device	Manufacturer	Type	FDA Status	Date
AquaFlow™	STAAR Surgical	Drainage device	PMA	2001
Ahmed™	New World Medical	Aqueous glaucoma shunt, ab externo	510(k)	<1993
Baerveldt®	Advanced Medical Optics	Aqueous glaucoma shunt, ab externo	510(k)	<1993
Krupin	Eagle Vision	Aqueous glaucoma shunt, ab externo	510(k)	<1993
Molteno®	Molteno Ophthalmic	Aqueous glaucoma shunt, ab externo	510(k)	<1993
EX-PRESS®	Alcon	Mini-glaucoma shunt, ab externo	510(k)	2003
XEN® Gel Stent; XEN injector	AqueSys/Allergan	Aqueous glaucoma stent, ab interno	510(k)	2016
iStent®; iStent inject®	Glaukos	Microstent, ab interno	515(d) in conjunction with cataract surgery	2018
iStent *supra*®	Glaukos	Suprachoroidal stent	Not approved; in clinical trial	
CyPass®	Alcon	Suprachoroidal stent, ab interno	Company voluntarily recalled	2018
Hydrus™	Ivantis	Microstent, ab interno	PMA approval	2018
Beacon Aqueous Microshunt	MicroOptx	Micro-Shunt, ab externo	Not approved; in clinical trial	
PRESERFLO® MicroShunt (previously InFocus)	Santen	Micro-Shunt, ab externo	Not approved; in clinical trial	
iStent Infinite	Glaukos	Microstent, ab interno	Not approved; in clinical trial	

FDA: Food and Drug Administration; PMA: premarket approval.
FDA product codes: OGO, KYF.

IV. RATIONALE

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Summary of Evidence

For individuals who have refractory open-angle glaucoma who receive ab externo aqueous shunts, the evidence includes randomized controlled trials (RCTs), retrospective studies, and systematic reviews. The relevant outcomes are a change in disease status, functional outcomes, medication use, and treatment-related morbidity. RCTs assessing U.S. Food and Drug Administration (FDA)-approved shunts have shown that the use of large externally placed shunts reduces IOP to slightly less than standard filtering surgery (trabeculectomy). Reported shunt success rates show that these devices are noninferior to trabeculectomy in the long-term. The FDA-approved shunts have different adverse event profiles and avoid some of the most problematic complications of trabeculectomy. Two trials have compared the Ahmed and Baerveldt shunts. Both found that eyes treated with the Baerveldt shunt had slightly lower average IOP at five years than eyes treated with the Ahmed but the Baerveldt also had a higher rate of serious hypotony-related complications. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have refractory open-angle glaucoma who receive ab interno aqueous stents, the evidence includes a nonrandomized retrospective comparative study and several single-arm studies. The relevant outcomes are a change in disease status, functional outcomes, medication use, and treatment-related morbidity. The comparative study reported that patients receiving the stent experienced similar reductions in IOP and medication use as patients undergoing trabeculectomy. The single-arm studies, with 12-month follow-up results, consistently showed that patients receiving the stents experienced reductions in IOP and medication use. Reductions in IOP ranged from 4 mm Hg to over 15 mm Hg. In addition, the FDA has given clearance to a gel stent based on equivalent IOP and medication use reductions as seen with ab externo shunts. Clearance for the stent was based on a review in which the FDA concluded that while there were technical differences between the stent and predicate devices (shunts), the differences did not affect safety and effectiveness in lowering IOP and medication use. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have mild-to-moderate OAG who are undergoing cataract surgery who receive aqueous microstents, the evidence includes RCTs and meta-analyses of RCTs. Relevant outcomes are a change in disease status, functional outcomes, medication use, and treatment-related morbidity. Implantation of 1 or 2 microstents has received the FDA approval for use in conjunction with cataract surgery for reduction of IOP in adults with mild-to-moderate OAG currently treated with ocular hypotensive medication. When compared to cataract surgery alone, the studies showed modest but statistically significant decreases in IOP and medication use through the first 2 years when stents were implanted in conjunction with cataract surgery. A decrease in topical medication application is considered to be an important outcome for patients and reduces the problem of non-compliance that can affect visual outcomes. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with mild-to-moderate OAG who are not undergoing cataract surgery who receive aqueous microstents as a stand-alone procedure, the evidence includes RCTs and a systematic review of 3 heterogeneous RCTs. Relevant outcomes are a change in disease status, functional outcomes, medication use, and treatment-related morbidity. Several RCTs have evaluated the use of multiple microstents but comparators differed. Two RCTs indicate that implantation of a microstent can reduce IOP at a level similar to ocular medications at 12-month follow-up. Reduction in medications is an important outcome for patients with glaucoma. Whether microstents remain patent after 12 months is uncertain, and whether additional stents can subsequently be safely implanted is unknown. Some evidence on longer-term outcomes is provided by an RCT that compared implantation of a single iStent to implantation of multiple iStents. At longer-term (42-month) follow-up, the need for additional medication increased in eyes implanted with a single microstent but not with multiple microstents. The durability of multiple iStents is unknown. A fourth RCT compared implantation of the Hydrus microstent to 2 iStents. Outcomes from the Hydrus microstent were significantly better than 2 iStents, both statistically and clinically, for all outcome measures. The primary limitation of this study is that the duration of follow-up in the publication is limited to 12 months. Longer-term follow-up from this study is continuing and will answer important questions on the durability of the procedure. Corroboration in an independent study and comparison with a medical therapy control group would also increase confidence in the results. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS Top

N/A

VI. BENEFIT VARIATIONS TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER TOP

Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a

member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary for FDA approved shunts and stents:

Procedure codes								
66179	66180	66183	66184	66185	0450T	0253T	0449T	0474T
0671T	66989	66991	C1783	L8612				

ICD-10-CM Diagnosis Codes	**Description**
B73.02	Onchocerciasis with glaucoma
H26.231	Glaucomatous flecks (subcapsular), right eye
H26.232	Glaucomatous flecks (subcapsular), left eye
H26.233	Glaucomatous flecks (subcapsular), bilateral
H26.239	Glaucomatous flecks (subcapsular), unspecified eye
H40.051	Ocular hypertension, right eye
H40.052	Ocular hypertension, left eye
H40.053	Ocular hypertension, bilateral
H40.059	Ocular hypertension, unspecified eye
H40.10X0	Unspecified open-angle glaucoma, stage unspecified
H40.10X1	Unspecified open-angle glaucoma, mild stage
H40.10X2	Unspecified open-angle glaucoma, moderate stage
H40.10X3	Unspecified open-angle glaucoma, severe stage
H40.10X4	Unspecified open-angle glaucoma, indeterminate stage
H40.1110	Primary open-angle glaucoma, right eye, stage unspecified
H40.1111	Primary open-angle glaucoma, right eye, mild stage
H40.1112	Primary open-angle glaucoma, right eye, moderate stage
H40.1113	Primary open-angle glaucoma, right eye, severe stage
H40.1114	Primary open-angle glaucoma, right eye, indeterminate stage

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ICD-10-CM Diagnosis Codes	Description
H40.1120	Primary open-angle glaucoma, left eye, stage unspecified
H40.1121	Primary open-angle glaucoma, left eye, mild stage
H40.1122	Primary open-angle glaucoma, left eye, moderate stage
H40.1123	Primary open-angle glaucoma, left eye, severe stage
H40.1124	Primary open-angle glaucoma, left eye, indeterminate stage
H40.1130	Primary open-angle glaucoma, bilateral, stage unspecified
H40.1131	Primary open-angle glaucoma, bilateral, mild stage
H40.1132	Primary open-angle glaucoma, bilateral, moderate stage
H40.1133	Primary open-angle glaucoma, bilateral, severe stage
H40.1134	Primary open-angle glaucoma, bilateral, indeterminate stage
H40.1190	Primary open-angle glaucoma, unspecified eye, stage unspecified
H40.1191	Primary open-angle glaucoma, unspecified eye, mild stage
H40.1192	Primary open-angle glaucoma, unspecified eye, moderate stage
H40.1193	Primary open-angle glaucoma, unspecified eye, severe stage
H40.1194	Primary open-angle glaucoma, unspecified eye, indeterminate stage
H40.1210	Low-tension glaucoma, right eye, stage unspecified
H40.1211	Low-tension glaucoma, right eye, mild stage
H40.1212	Low-tension glaucoma, right eye, moderate stage
H40.1213	Low-tension glaucoma, right eye, severe stage
H40.1214	Low-tension glaucoma, right eye, indeterminate stage
H40.1220	Low-tension glaucoma, left eye, stage unspecified
H40.1221	Low-tension glaucoma, left eye, mild stage
H40.1222	Low-tension glaucoma, left eye, moderate stage
H40.1223	Low-tension glaucoma, left eye, severe stage
H40.1224	Low-tension glaucoma, left eye, indeterminate stage
H40.1230	Low-tension glaucoma, bilateral, stage unspecified
H40.1231	Low-tension glaucoma, bilateral, mild stage
H40.1232	Low-tension glaucoma, bilateral, moderate stage
H40.1233	Low-tension glaucoma, bilateral, severe stage
H40.1234	Low-tension glaucoma, bilateral, indeterminate stage
H40.1290	Low-tension glaucoma, unspecified eye, stage unspecified
H40.1291	Low-tension glaucoma, unspecified eye, mild stage
H40.1292	Low-tension glaucoma, unspecified eye, moderate stage
H40.1293	Low-tension glaucoma, unspecified eye, severe stage
H40.1294	Low-tension glaucoma, unspecified eye, indeterminate stage
H40.1310	Pigmentary glaucoma, right eye, stage unspecified
H40.1311	Pigmentary glaucoma, right eye, mild stage

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ICD-10-CM Diagnosis Codes	Description
H40.1312	Pigmentary glaucoma, right eye, moderate stage
H40.1313	Pigmentary glaucoma, right eye, severe stage
H40.1314	Pigmentary glaucoma, right eye, indeterminate stage
H40.1320	Pigmentary glaucoma, left eye, stage unspecified
H40.1321	Pigmentary glaucoma, left eye, mild stage
H40.1322	Pigmentary glaucoma, left eye, moderate stage
H40.1323	Pigmentary glaucoma, left eye, severe stage
H40.1324	Pigmentary glaucoma, left eye, indeterminate stage
H40.1330	Pigmentary glaucoma, bilateral, stage unspecified
H40.1331	Pigmentary glaucoma, bilateral, mild stage
H40.1332	Pigmentary glaucoma, bilateral, moderate stage
H40.1333	Pigmentary glaucoma, bilateral, severe stage
H40.1334	Pigmentary glaucoma, bilateral, indeterminate stage
H40.1390	Pigmentary glaucoma, unspecified eye, stage unspecified
H40.1391	Pigmentary glaucoma, unspecified eye, mild stage
H40.1392	Pigmentary glaucoma, unspecified eye, moderate stage
H40.1393	Pigmentary glaucoma, unspecified eye, severe stage
H40.1394	Pigmentary glaucoma, unspecified eye, indeterminate stage
H40.1410	Capsular glaucoma with pseudoexfoliation of lens, right eye, stage unspecified
H40.1411	Capsular glaucoma with pseudoexfoliation of lens, right eye, mild stage
H40.1412	Capsular glaucoma with pseudoexfoliation of lens, right eye, moderate stage
H40.1413	Capsular glaucoma with pseudoexfoliation of lens, right eye, severe stage
H40.1414	Capsular glaucoma with pseudoexfoliation of lens, right eye, indeterminate stage
H40.1420	Capsular glaucoma with pseudoexfoliation of lens, left eye, stage unspecified
H40.1421	Capsular glaucoma with pseudoexfoliation of lens, left eye, mild stage
H40.1422	Capsular glaucoma with pseudoexfoliation of lens, left eye, moderate stage
H40.1423	Capsular glaucoma with pseudoexfoliation of lens, left eye, severe stage
H40.1424	Capsular glaucoma with pseudoexfoliation of lens, left eye, indeterminate stage
H40.1430	Capsular glaucoma with pseudoexfoliation of lens, bilateral, stage unspecified
H40.1431	Capsular glaucoma with pseudoexfoliation of lens, bilateral, mild stage
H40.1432	Capsular glaucoma with pseudoexfoliation of lens, bilateral, moderate stage
H40.1433	Capsular glaucoma with pseudoexfoliation of lens, bilateral, severe stage
H40.1434	Capsular glaucoma with pseudoexfoliation of lens, bilateral, indeterminate stage
H40.1490	Capsular glaucoma with pseudoexfoliation of lens, unspecified eye, stage unspecified
H40.1491	Capsular glaucoma with pseudoexfoliation of lens, unspecified eye, mild stage
H40.1492	Capsular glaucoma with pseudoexfoliation of lens, unspecified eye, moderate stage
H40.1493	Capsular glaucoma with pseudoexfoliation of lens, unspecified eye, severe stage

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ICD-10-CM Diagnosis Codes	Description
H40.1494	Capsular glaucoma with pseudoexfoliation of lens, unspecified eye, indeterminate stage
H40.151	Residual stage of open-angle glaucoma, right eye
H40.152	Residual stage of open-angle glaucoma, left eye
H40.153	Residual stage of open-angle glaucoma, bilateral
H40.159	Residual stage of open-angle glaucoma, unspecified eye
H40.20X0	Unspecified primary angle-closure glaucoma, stage unspecified
H40.20X1	Unspecified primary angle-closure glaucoma, mild stage
H40.20X2	Unspecified primary angle-closure glaucoma, moderate stage
H40.20X3	Unspecified primary angle-closure glaucoma, severe stage
H40.20X4	Unspecified primary angle-closure glaucoma, indeterminate stage
H40.211	Acute angle-closure glaucoma, right eye
H40.212	Acute angle-closure glaucoma, left eye
H40.213	Acute angle-closure glaucoma, bilateral
H40.219	Acute angle-closure glaucoma, unspecified eye
H40.2210	Chronic angle-closure glaucoma, right eye, stage unspecified
H40.2211	Chronic angle-closure glaucoma, right eye, mild stage
H40.2212	Chronic angle-closure glaucoma, right eye, moderate stage
H40.2213	Chronic angle-closure glaucoma, right eye, severe stage
H40.2214	Chronic angle-closure glaucoma, right eye, indeterminate stage
H40.2220	Chronic angle-closure glaucoma, left eye, stage unspecified
H40.2221	Chronic angle-closure glaucoma, left eye, mild stage
H40.2222	Chronic angle-closure glaucoma, left eye, moderate stage
H40.2223	Chronic angle-closure glaucoma, left eye, severe stage
H40.2224	Chronic angle-closure glaucoma, left eye, indeterminate stage
H40.2230	Chronic angle-closure glaucoma, bilateral, stage unspecified
H40.2231	Chronic angle-closure glaucoma, bilateral, mild stage
H40.2232	Chronic angle-closure glaucoma, bilateral, moderate stage
H40.2233	Chronic angle-closure glaucoma, bilateral, severe stage
H40.2234	Chronic angle-closure glaucoma, bilateral, indeterminate stage
H40.2290	Chronic angle-closure glaucoma, unspecified eye, stage unspecified
H40.2291	Chronic angle-closure glaucoma, unspecified eye, mild stage
H40.2292	Chronic angle-closure glaucoma, unspecified eye, moderate stage
H40.2293	Chronic angle-closure glaucoma, unspecified eye, severe stage
H40.2294	Chronic angle-closure glaucoma, unspecified eye, indeterminate stage
H40.231	Intermittent angle-closure glaucoma, right eye
H40.232	Intermittent angle-closure glaucoma, left eye

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ICD-10-CM Diagnosis Codes	Description
H40.233	Intermittent angle-closure glaucoma, bilateral
H40.239	Intermittent angle-closure glaucoma, unspecified eye
H40.241	Residual stage of angle-closure glaucoma, right eye
H40.242	Residual stage of angle-closure glaucoma, left eye
H40.243	Residual stage of angle-closure glaucoma, bilateral
H40.249	Residual stage of angle-closure glaucoma, unspecified eye
H40.30X0	Glaucoma secondary to eye trauma, unspecified eye, stage unspecified
H40.30X1	Glaucoma secondary to eye trauma, unspecified eye, mild stage
H40.30X2	Glaucoma secondary to eye trauma, unspecified eye, moderate stage
H40.30X3	Glaucoma secondary to eye trauma, unspecified eye, severe stage
H40.30X4	Glaucoma secondary to eye trauma, unspecified eye, indeterminate stage
H40.31X0	Glaucoma secondary to eye trauma, right eye, stage unspecified
H40.31X1	Glaucoma secondary to eye trauma, right eye, mild stage
H40.31X2	Glaucoma secondary to eye trauma, right eye, moderate stage
H40.31X3	Glaucoma secondary to eye trauma, right eye, severe stage
H40.31X4	Glaucoma secondary to eye trauma, right eye, indeterminate stage
H40.32X0	Glaucoma secondary to eye trauma, left eye, stage unspecified
H40.32X1	Glaucoma secondary to eye trauma, left eye, mild stage
H40.32X2	Glaucoma secondary to eye trauma, left eye, moderate stage
H40.32X3	Glaucoma secondary to eye trauma, left eye, severe stage
H40.32X4	Glaucoma secondary to eye trauma, left eye, indeterminate stage
H40.33X0	Glaucoma secondary to eye trauma, bilateral, stage unspecified
H40.33X1	Glaucoma secondary to eye trauma, bilateral, mild stage
H40.33X2	Glaucoma secondary to eye trauma, bilateral, moderate stage
H40.33X3	Glaucoma secondary to eye trauma, bilateral, severe stage
H40.33X4	Glaucoma secondary to eye trauma, bilateral, indeterminate stage
H40.40X0	Glaucoma secondary to eye inflammation, unspecified eye, stage unspecified
H40.40X1	Glaucoma secondary to eye inflammation, unspecified eye, mild stage
H40.40X2	Glaucoma secondary to eye inflammation, unspecified eye, moderate stage
H40.40X3	Glaucoma secondary to eye inflammation, unspecified eye, severe stage
H40.40X4	Glaucoma secondary to eye inflammation, unspecified eye, indeterminate stage
H40.41X0	Glaucoma secondary to eye inflammation, right eye, stage unspecified
H40.41X1	Glaucoma secondary to eye inflammation, right eye, mild stage
H40.41X2	Glaucoma secondary to eye inflammation, right eye, moderate stage
H40.41X3	Glaucoma secondary to eye inflammation, right eye, severe stage
H40.41X4	Glaucoma secondary to eye inflammation, right eye, indeterminate stage
H40.42X0	Glaucoma secondary to eye inflammation, left eye, stage unspecified

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ICD-10-CM Diagnosis Codes	Description
H40.42X1	Glaucoma secondary to eye inflammation, left eye, mild stage
H40.42X2	Glaucoma secondary to eye inflammation, left eye, moderate stage
H40.42X3	Glaucoma secondary to eye inflammation, left eye, severe stage
H40.42X4	Glaucoma secondary to eye inflammation, left eye, indeterminate stage
H40.43X0	Glaucoma secondary to eye inflammation, bilateral, stage unspecified
H40.43X1	Glaucoma secondary to eye inflammation, bilateral, mild stage
H40.43X2	Glaucoma secondary to eye inflammation, bilateral, moderate stage
H40.43X3	Glaucoma secondary to eye inflammation, bilateral, severe stage
H40.43X4	Glaucoma secondary to eye inflammation, bilateral, indeterminate stage
H40.50X0	Glaucoma secondary to other eye disorders, unspecified eye, stage unspecified
H40.50X1	Glaucoma secondary to other eye disorders, unspecified eye, mild stage
H40.50X2	Glaucoma secondary to other eye disorders, unspecified eye, moderate stage
H40.50X3	Glaucoma secondary to other eye disorders, unspecified eye, severe stage
H40.50X4	Glaucoma secondary to other eye disorders, unspecified eye, indeterminate stage
H40.51X0	Glaucoma secondary to other eye disorders, right eye, stage unspecified
H40.51X1	Glaucoma secondary to other eye disorders, right eye, mild stage
H40.51X2	Glaucoma secondary to other eye disorders, right eye, moderate stage
H40.51X3	Glaucoma secondary to other eye disorders, right eye, severe stage
H40.51X4	Glaucoma secondary to other eye disorders, right eye, indeterminate stage
H40.52X0	Glaucoma secondary to other eye disorders, left eye, stage unspecified
H40.52X1	Glaucoma secondary to other eye disorders, left eye, mild stage
H40.52X2	Glaucoma secondary to other eye disorders, left eye, moderate stage
H40.52X3	Glaucoma secondary to other eye disorders, left eye, severe stage
H40.52X4	Glaucoma secondary to other eye disorders, left eye, indeterminate stage
H40.53X0	Glaucoma secondary to other eye disorders, bilateral, stage unspecified
H40.53X1	Glaucoma secondary to other eye disorders, bilateral, mild stage
H40.53X2	Glaucoma secondary to other eye disorders, bilateral, moderate stage
H40.53X3	Glaucoma secondary to other eye disorders, bilateral, severe stage
H40.53X4	Glaucoma secondary to other eye disorders, bilateral, indeterminate stage
H40.60X0	Glaucoma secondary to drugs, unspecified eye, stage unspecified
H40.60X1	Glaucoma secondary to drugs, unspecified eye, mild stage
H40.60X2	Glaucoma secondary to drugs, unspecified eye, moderate stage
H40.60X3	Glaucoma secondary to drugs, unspecified eye, severe stage
H40.60X4	Glaucoma secondary to drugs, unspecified eye, indeterminate stage
H40.61X0	Glaucoma secondary to drugs, right eye, stage unspecified
H40.61X1	Glaucoma secondary to drugs, right eye, mild stage
H40.61X2	Glaucoma secondary to drugs, right eye, moderate stage

ICD-10-CM Diagnosis Codes	Description
H40.61X3	Glaucoma secondary to drugs, right eye, severe stage
H40.61X4	Glaucoma secondary to drugs, right eye, indeterminate stage
H40.62X0	Glaucoma secondary to drugs, left eye, stage unspecified
H40.62X1	Glaucoma secondary to drugs, left eye, mild stage
H40.62X2	Glaucoma secondary to drugs, left eye, moderate stage
H40.62X3	Glaucoma secondary to drugs, left eye, severe stage
H40.62X4	Glaucoma secondary to drugs, left eye, indeterminate stage
H40.63X0	Glaucoma secondary to drugs, bilateral, stage unspecified
H40.63X1	Glaucoma secondary to drugs, bilateral, mild stage
H40.63X2	Glaucoma secondary to drugs, bilateral, moderate stage
H40.63X3	Glaucoma secondary to drugs, bilateral, severe stage
H40.63X4	Glaucoma secondary to drugs, bilateral, indeterminate stage
H40.811	Glaucoma with increased episcleral venous pressure, right eye
H40.812	Glaucoma with increased episcleral venous pressure, left eye
H40.813	Glaucoma with increased episcleral venous pressure, bilateral
H40.819	Glaucoma with increased episcleral venous pressure, unspecified eye
H40.821	Hypersecretion glaucoma, right eye
H40.822	Hypersecretion glaucoma, left eye
H40.823	Hypersecretion glaucoma, bilateral
H40.829	Hypersecretion glaucoma, unspecified eye
H40.831	Aqueous misdirection, right eye
H40.832	Aqueous misdirection, left eye
H40.833	Aqueous misdirection, bilateral
H40.839	Aqueous misdirection, unspecified eye
H40.89	Other specified glaucoma
H40.9	Unspecified glaucoma
H42	Glaucoma in diseases classified elsewhere

IX. REFERENCES

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1. *Allison K, Patel DG, Greene L. Racial and Ethnic Disparities in Primary Open-Angle Glaucoma Clinical Trials: A Systematic Review and Meta-analysis. JAMA Netw Open. May 03 2021; 4(5): e218348. PMID 34003274*
2. *Minckler DS, Vedula SS, Li TJ, et al. Aqueous shunts for glaucoma. Cochrane Database Syst Rev. Apr 19 2006; (2): CD004918. PMID 16625616*
3. *Minckler DS, Francis BA, Hodapp EA, et al. Aqueous shunts in glaucoma: a report by the American Academy of Ophthalmology. Ophthalmology. Jun 2008; 115(6): 1089-98. PMID 18519069*

4. *Zhang X, Wang B, Liu R, et al. The effectiveness of AGV, Ex-PRESS, or trabeculectomy in the treatment of primary and secondary glaucoma: a systematic review and network meta-analysis. Ann Palliat Med. Jan 2022; 11(1): 321-331. PMID 35144423*
5. *Boland MV, Ervin AM, Friedman D, et al. Treatment for Glaucoma: Comparative Effectiveness. Comparative Effectiveness Review No. 60 (AHRQ Publication No. 12-EHC038-EF). Rockville, MD: Agency for Healthcare Research and Quality; 2012.*
6. *Gedde SJ, Schiffman JC, Feuer WJ, et al. Treatment outcomes in the Tube Versus Trabeculectomy (TVT) study after five years of follow-up. Am J Ophthalmol. May 2012; 153(5): 789-803.e2. PMID 22245458*
7. *Kotecha A, Feuer WJ, Barton K, et al. Quality of Life in the Tube Versus Trabeculectomy Study. Am J Ophthalmol. Apr 2017; 176: 228-235. PMID 28161049*
8. *Swaminathan SS, Jammal AA, Kornmann HL, et al. Visual Field Outcomes in the Tube Versus Trabeculectomy Study. Ophthalmology. Sep 2020; 127(9): 1162-1169. PMID 32327255*
9. *Wang X, Khan R, Coleman A. Device-modified trabeculectomy for glaucoma. Cochrane Database Syst Rev. Dec 01 2015; (12): CD010472. PMID 26625212*
10. *Netland PA, Sarkisian SR, Moster MR, et al. Randomized, prospective, comparative trial of EX-PRESS glaucoma filtration device versus trabeculectomy (XVT study). Am J Ophthalmol. Feb 2014; 157(2): 433-440.e3. PMID 24210765*
11. *de Jong LA. The Ex-PRESS glaucoma shunt versus trabeculectomy in open-angle glaucoma: a prospective randomized study. Adv Ther. Mar 2009; 26(3): 336-45. PMID 19337705*
12. *de Jong L, Lafuma A, Aguade AS, et al. Five-year extension of a clinical trial comparing the EX-PRESS glaucoma filtration device and trabeculectomy in primary open-angle glaucoma. Clin Ophthalmol. 2011; 5: 527-33. PMID 21607021*
13. *Wagschal LD, Trope GE, Jinapriya D, et al. Prospective Randomized Study Comparing Ex-PRESS to Trabeculectomy: 1-Year Results. J Glaucoma. Oct-Nov 2015; 24(8): 624-9. PMID 24247999*
14. *Gonzalez-Rodriguez JM, Trope GE, Drori-Wagschal L, et al. Comparison of trabeculectomy versus Ex-PRESS: 3-year follow-up. Br J Ophthalmol. Sep 2016; 100(9): 1269-73. PMID 26674779*
15. *Konopinska J, Byszewska A, Saeed E, et al. Phacotrabeculectomy versus Phaco with Implantation of the Ex-PRESS Device: Surgical and Refractive Outcomes-A Randomized Controlled Trial. J Clin Med. Jan 22 2021; 10(3). PMID 33499300*
16. *Budenz DL, Barton K, Gedde SJ, et al. Five-year treatment outcomes in the Ahmed Baerveldt comparison study. Ophthalmology. Feb 2015; 122(2): 308-16. PMID 25439606*
17. *Budenz DL, Feuer WJ, Barton K, et al. Postoperative Complications in the Ahmed Baerveldt Comparison Study During Five Years of Follow-up. Am J Ophthalmol. Mar 2016; 163: 75-82.e3. PMID 26596400*
18. *Christakis PG, Kalenak JW, Tsai JC, et al. The Ahmed Versus Baerveldt Study: Five-Year Treatment Outcomes. Ophthalmology. Oct 2016; 123(10): 2093-102. PMID 27544023*

19. *Christakis PG, Zhang D, Budenz DL, et al. Five-Year Pooled Data Analysis of the Ahmed Baerveldt Comparison Study and the Ahmed Versus Baerveldt Study. Am J Ophthalmol. Apr 2017; 176: 118-126. PMID 28104418*
20. *Lim SY, Betzler BK, Yip LWL, et al. Standalone XEN45 Gel Stent implantation in the treatment of open-angle glaucoma: A systematic review and meta-analysis. Surv Ophthalmol. Jul-Aug 2022; 67(4): 1048-1061. PMID 35081414*
21. *Yang X, Zhao Y, Zhong Y, et al. The efficacy of XEN gel stent implantation in glaucoma: a systematic review and meta-analysis. BMC Ophthalmol. Jul 15 2022; 22(1): 305. PMID 35836197*
22. *Schlenker MB, Gulamhusein H, Conrad-Hengerer I, et al. Efficacy, Safety, and Risk Factors for Failure of Standalone Ab Interno Gelatin Microstent Implantation versus Standalone Trabeculectomy. Ophthalmology. Nov 2017; 124(11): 1579-1588. PMID 28601250*
23. *Wagner FM, Schuster AK, Emmerich J, et al. Efficacy and safety of XEN(R)-Implantation vs. trabeculectomy: Data of a "real-world" setting. PLoS One. 2020; 15(4): e0231614. PMID 32310972*
24. *Stoner AM, Capitena Young CE, SooHoo JR, et al. A Comparison of Clinical Outcomes After XEN Gel Stent and EX-PRESS Glaucoma Drainage Device Implantation. J Glaucoma. Jun 01 2021; 30(6): 481-488. PMID 34060508*
25. *Gabbay IE, Goldberg M, Allen F, et al. Efficacy and safety data for the Ab interno XEN45 gel stent implant at 3 Years: A retrospective analysis. Eur J Ophthalmol. May 02 2021: 11206721211014381. PMID 33938304*
26. *Le JT, Bicket AK, Wang L, et al. Ab interno trabecular bypass surgery with iStent for open-angle glaucoma. Cochrane Database Syst Rev. Mar 28 2019; 3: CD012743. PMID 30919929*
27. *Healey PR, Clement CI, Kerr NM, et al. Standalone iStent Trabecular Micro-bypass Glaucoma Surgery: A Systematic Review and Meta-Analysis. J Glaucoma. Jul 01 2021; 30(7): 606-620. PMID 33596009*
28. *Samuelson TW, Katz LJ, Wells JM, et al. Randomized evaluation of the trabecular micro-bypass stent with phacoemulsification in patients with glaucoma and cataract. Ophthalmology. Mar 2011; 118(3): 459-67. PMID 20828829*
29. *Craven ER, Katz LJ, Wells JM, et al. Cataract surgery with trabecular micro-bypass stent implantation in patients with mild-to-moderate open-angle glaucoma and cataract: two-year follow-up. J Cataract Refract Surg. Aug 2012; 38(8): 1339-45. PMID 22814041*
30. *Samuelson TW, Sarkisian SR, Lubeck DM, et al. Prospective, Randomized, Controlled Pivotal Trial of an Ab Interno Implanted Trabecular Micro-Bypass in Primary Open-Angle Glaucoma and Cataract: Two-Year Results. Ophthalmology. Jun 2019; 126(6): 811-821. PMID 30880108*
31. *Hooshmand J, Rothschild P, Allen P, et al. Minimally invasive glaucoma surgery: Comparison of iStent with iStent inject in primary open angle glaucoma. Clin Exp Ophthalmol. Sep 2019; 47(7): 898-903. PMID 31034687*
32. *Al Yousef Y, Strzalkowska A, Hillenkamp J, et al. Comparison of a second-generation trabecular bypass (iStent inject) to ab interno trabeculectomy (Trabectome) by exact*

matching. Graefes Arch Clin Exp Ophthalmol. Dec 2020; 258(12): 2775-2780. PMID 32960322

33. *Salimi A, Watt H, Harasymowycz P. Three-Year Outcomes of Second-generation Trabecular Micro-bypass Stents (iStent inject) With Phacoemulsification in Various Glaucoma Subtypes and Severities. J Glaucoma. Mar 01 2021; 30(3): 266-275. PMID 33105306*
34. *Otarola F, Virgili G, Shah A, et al. Ab interno trabecular bypass surgery with Schlemms canal microstent (Hydrus) for open angle glaucoma. Cochrane Database Syst Rev. Mar 09 2020; 3: CD012740. PMID 32147807*
35. *Pfeiffer N, Garcia-Feijoo J, Martinez-de-la-Casa JM, et al. A Randomized Trial of a Schlemm's Canal Microstent with Phacoemulsification for Reducing Intraocular Pressure in Open-Angle Glaucoma. Ophthalmology. Jul 2015; 122(7): 1283-93. PMID 25972254*
36. *Samuelson TW, Chang DF, Marquis R, et al. A Schlemm Canal Microstent for Intraocular Pressure Reduction in Primary Open-Angle Glaucoma and Cataract: The HORIZON Study. Ophthalmology. Jan 2019; 126(1): 29-37. PMID 29945799*
37. *Ahmed IIK, Fea A, Au L, et al. A Prospective Randomized Trial Comparing Hydrus and iStent Microinvasive Glaucoma Surgery Implants for Standalone Treatment of Open-Angle Glaucoma: The COMPARE Study. Ophthalmology. Jan 2020; 127(1): 52-61. PMID 31034856*
38. *Fea AM, Ahmed II, Lavia C, et al. Hydrus microstent compared to selective laser trabeculoplasty in primary open angle glaucoma: one year results. Clin Exp Ophthalmol. Mar 2017; 45(2): 120-127. PMID 27449488*
39. *Fea AM, Belda JI, Rekas M, et al. Prospective unmasked randomized evaluation of the iStent inject ((R)) versus two ocular hypotensive agents in patients with primary open-angle glaucoma. Clin Ophthalmol. 2014; 8: 875-82. PMID 24855336*
40. *Vold SD, Voskanyan L, Tetz M, et al. Newly Diagnosed Primary Open-Angle Glaucoma Randomized to 2 Trabecular Bypass Stents or Prostaglandin: Outcomes Through 36 Months. Ophthalmol Ther. Dec 2016; 5(2): 161-172. PMID 27619225*
41. *Berdahl J, Voskanyan L, Myers JS, et al. iStent inject trabecular micro-bypass stents with topical prostaglandin as standalone treatment for open-angle glaucoma: 4-year outcomes. Clin Exp Ophthalmol. Aug 2020; 48(6): 767-774. PMID 32311201*
42. *Lindstrom R, Sarkisian SR, Lewis R, et al. Four-Year Outcomes of Two Second-Generation Trabecular Micro-Bypass Stents in Patients with Open-Angle Glaucoma on One Medication. Clin Ophthalmol. 2020; 14: 71-80. PMID 32021070*
43. *Katz LJ, Erb C, Carceller GA, et al. Prospective, randomized study of one, two, or three trabecular bypass stents in open-angle glaucoma subjects on topical hypotensive medication. Clin Ophthalmol. 2015; 9: 2313-20. PMID 26715834*
44. *Katz LJ, Erb C, Carceller Guillamet A, et al. Long-term titrated IOP control with one, two, or three trabecular micro-bypass stents in open-angle glaucoma subjects on topical hypotensive medication: 42-month outcomes. Clin Ophthalmol. 2018; 12: 255-262. PMID 29440867*

45. Gedde SJ, Vinod K, Wright MM, et al. Primary open-angle glaucoma preferred practice pattern. September 2020. https://www.aao.org/preferred-practice-pattern/primary-open-angle-glaucoma-ppp.
46. Fellman RL, Mattox C, Singh K, et al. American Glaucoma Society Position Paper: Microinvasive Glaucoma Surgery. Ophthalmol Glaucoma. Jan 2020; 3(1): 1-6. PMID 32672638
47. National Institute for Health and Care Evidence (NICE). Trabecular stent bypass microsurgery for open-angle glaucoma [IPG575]. 2017;
48. National Institute for Health and Care Excellence. Microinvasive subconjunctival insertion of a trans-sceral gelatin stent for primary open-angle glaucoma. [IPG612]. 2018;
49. Pereira ICF, van Mechelen RJS, Wyss HM, Pinchuk L, Beckers HJM, den Toonder JMJ. Magnetically actuated glaucoma drainage device for regulating intraocular pressure after implantation. Microsyst Nanoeng. 2023;9:92. Published 2023 Jul 20. doi:10.1038/s41378-023-00561-9
50. Blue Cross Blue Shield Association Medical Policy Reference Manual. 9.03.21. Aqueous Shunts and Stents for Glaucoma. October 2023.

X. POLICY HISTORY

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MP-2.149	**3/6/2020** Consensus Review. Policy statement unchanged. References updated. Coding updated.
	06/15/2021 Coding updated: Added new codes 0660T and 0661T
	11/22/2021 Consensus Review. 0660T and 0661T removed from policy and placed on E/I policy. Background, rationale and references updated.
	12/1/2021 Administrative Update. Deleted codes 0191T, 0376T. Added codes 0671T, 66989, 66991. Removed 0660T and 0661T and moved to E/I policy.
	11/28/2022 Consensus review. Background, rationale, and references updated.
	10/16/2023 Consensus review. No changes to policy statement. Updated references. Coding reviewed, no changes.

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APPENDIX

Aqueous Shunts and Stents Not Approved by FDA

iStent as Stand-Alone Glaucoma Surgery

The iStent was approved by the FDA to be used in conjunction with cataract surgery to reduce IOP in patients with mild-to-moderate open-angle glaucoma. The studies described below evaluated the use of the iStent as a stand-alone procedure.

A 2014 industry-sponsored, multicenter, unblinded, randomized trial compared implantation of 2 iStent *inject* devices with 2 ocular hypotensive agents. The 192 patients enrolled in this unmasked trial had an IOP not controlled by 1 hypotensive medication. At 12-month follow-up, the 2 groups were comparable for IOP reduction of at least 20%, IOP of 18 mm Hg or less, and mean decrease in IOP. A greater proportion of patients in the iStent *inject* group achieved an IOP reduction of at least 50% (53.2% vs 35.7%, respectively). One patient in the iStent *inject* group experienced elevated IOP (48 mm Hg) and 4 required ocular hypotensive medication. Longer-term studies are in progress.

Vold et al (2016) reported on results of an RCT comparing 2 stand-alone iStent implants to topical travoprost (1:1 ratio) in 101 phakic eyes with an IOP between 21 and 40 mm Hg and newly diagnosed primary open-angle glaucoma, pseudoexfoliative glaucoma, or ocular hypertension that had not been treated previously. The patients were not undergoing cataract surgery. The trial was unmasked, and methods for allocation concealment and calculation of power were not described. One hundred patients (54 iStent; 47 travoprost) completed 24 months of follow-up and 73 completed 36 months of follow-up. The trial was performed at a single center in Armenia. Statistical analyses were not provided. Baseline mean IOP was 25 mm Hg in both groups. Mean IOP at 3 years was 15 mm Hg in both groups. Medication (or second medication) was addedto 6 eyes in the iStent group and 11 eyes in the travoprost group. Progression of cataract was reported in 11 eyes in the iStent group and 8 eyes in the travoprost group, with cataract surgery being performed in 5 eyes in the iStent group and 1 eye in the travoprost group. The results would suggest that 2 iStents might reduce the number of medications required to maintain target IOP compared with travoprost but also hasten time to cataract surgery. However, the study methods were poorly reported, and statistical analyses were not reported. The study was funded by the iStent manufacturer.

Gonnermann et al (2017) conducted a retrospective study on 27 patients with moderate open-angle glaucoma and cataracts who underwent trabeculectomy in 1 eye and implantation of 2 iStent inject devices in the other eye. Outcomes of interest were IOP and glaucoma medication use through 12 months of follow-up. Mean IOP and number of antiglaucoma medications decreased significantly with both treatments. There was no statistically significant difference in outcomes between groups, supporting the noninferiority of the iStent *inject* to trabeculectomy.

Donnenfeld et al (2015) published a prospective case series enrolling 39 patients with open-angle glaucoma and IOP between 18 and 30 mm Hg.38. Each patient received 2 microstents and medications as needed, and was followed for 3 years. At trial completion, mean reduction in IOP was 9.1 mm Hg (95% CI, 8.0 to 10.1 mm Hg). There was 1 postoperative complication (hyphema), which resolved without further intervention.

Two case series evaluating the use of 2 iStent *inject* devices for treatment of patients with uncontrolled open-angle glaucoma in stand-alone procedures were published in 2017. Berdahl et al (2017) treated 53 patients and reported that 91% of patients achieved an IOP reduction of at least 20% at the 12-month follow-up. Chang et al (2017) treated 39 patients and reported that 97% of patients achieved an IOP reduction of at least 20% after 3 years of follow-up. No device-related adverse events were reported in either study.

iStent supra

Myers et al (2018) presented 4-year outcomes of a single-arm study implanting 2 iStent trabecular micro-bypass stents and 1 iStent *supra* suprachoroidal stent in 80 patients with refractory glaucoma.[55] At 4-years follow-up, patients experienced a 37% or more mean reduction in IOP. All patients received travoprost following the procedure, with 6 patients requiring additional medication when IOP exceeded 21 mm Hg. No intraoperative adverse events were reported.

Hydrus Microstent as Stand-Alone Glaucoma Surgery

The Hydrus microstent was approved by the FDA to be used in conjunction with cataract surgery to reduce IOP in patients with mild-to-moderate open-angle glaucoma. The study described below evaluated the use of the Hydrus Microstent as a stand-alone procedure.

Fea et al (2017) conducted a 2-center study in which 56 patients with uncontrolled primary open-angle glaucoma received either laser trabeculoplasty or a Hydrus Microstent, depending on the center at which the patient was seen. Patients were followed for 12 months postsurgery and evaluated for IOP and glaucoma medication use. Both treatments resulted in significant reductions in IOP; however, only patients receiving the microstent experienced significant reductions in medication use. No complications were reported in the trabeculoplasty group. In the microstent group, temporary reductions in visual acuity and IOP spikes occurred.

SOLX Gold Shunt

Tanito et al (2017) published results from a 2-center single-arm study in which 24 patients with refractory open-angle glaucoma received the SOLX GoldShunt. Outcomes evaluated at baseline through 1 year of follow-up included medication use, IOP, and surgical complications. IOP was significantly reduced at every follow-up visit, with an average 23% reduction from baseline at 1-year follow-up ($p<0.001$). Patients also experienced a 40% reduction in medication use at 1-year follow-up from baseline ($p<0.001$). Inflammation-related complications were reported.